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APPLICATION NO), F	ILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/613,380		07/03/2003	Wendell Lim	UCSF03-114	5261
23379	7590	04/28/2006		EXAMINER	
	D ARON	 	SKIBINSKY, ANNA		
SCIENCE AND TECHNOLOGY LAW GROUP 242 AVE VISTA DEL OCEANO				ART UNIT	PAPER NUMBER
SAN CLE	SAN CLEMEMTE, CA 92672			1631	
				DATE MAILED: 04/28/2006	5

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)
	10/613,380	LIM ET AL.
Office Action Summary	Examiner	Art Unit
	Anna Skibinsky	1631
The MAILING DATE of this communication	appears on the cover sheet wi	th the correspondence address
Period for Reply		
A SHORTENED STATUTORY PERIOD FOR RE WHICHEVER IS LONGER, FROM THE MAILING - Extensions of time may be available under the provisions of 37 CFF after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory per - Failure to reply within the set or extended period for reply will, by state of the period for reply will, by state of the period for reply will. Set on the period for reply will by state of the period for reply will. Set of the period for reply will be stated than three months after the meanned patent term adjustment. See 37 CFR 1.704(b).	B DATE OF THIS COMMUNIC R 1.136(a). In no event, however, may a re- riod will apply and will expire SIX (6) MON atute, cause the application to become AB	CATION. eply be timely filed THS from the mailing date of this communication. ANDONED (35 U.S.C. § 133).
Status		:
1) Responsive to communication(s) filed on 0:	5 February 2006.	:
•	his action is non-final.	•
3) Since this application is in condition for allo	wance except for formal matt	ers, prosecution as to the merits is
closed in accordance with the practice unde	er <i>Ex par</i> te Quayle, 1935 C.D	. 11, 453 O.G. 213.
Disposition of Claims		
·	ion	:
 4) Claim(s) 1-13 is/are pending in the applicat 4a) Of the above claim(s) 3-5,7 and 9-13 is/ 		etion :
5) Claim(s) is/are allowed.	are withdrawn from considere	
6)⊠ Claim(s) <u>1,2,6 and 8</u> is/are rejected.		· •
7) Claim(s) is/are objected to.		
8) Claim(s) are subject to restriction an	d/or election requirement.	<u>.</u>
o, <u> </u>	·	:
Application Papers		
9) The specification is objected to by the Exam		:
10) ☐ The drawing(s) filed on is/are: a) ☐ a		•
Applicant may not request that any objection to		
Replacement drawing sheet(s) including the cor		
11)☐ The oath or declaration is objected to by the	Examiner. Note the attached	Office Action or form PTO-152.
Priority under 35 U.S.C. § 119		
12) Acknowledgment is made of a claim for fore	eign priority under 35 U.S.C. §	119(a)-(d) or (f)
a) All b) Some * c) None of:	ente have been received	:
 Certified copies of the priority docum Certified copies of the priority docum 		polication No.
2. Certified copies of the priority docum3. Copies of the certified copies of the priority docum		
application from the International But	•	Toolived III and Italienal etage
* See the attached detailed Office action for a	•	received.
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Attachment(s)	-	:
 Notice of References Cited (PTO-892) Notice of Draftsperson's Patent Drawing Review (PTO-948) 	,	Summary (PTO-413) s)/Mail Date
3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB	(/08) 5) Notice of I	nformal Patent Application (PTO-152)
Paper No(s)/Mail Date	6) [] Other:	<u> </u>

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DETAILED ACTION

Reply to Applicant

Applicant was required to make two restrictions:

- 1. Applicant's election of Group I, specie 1A, 2B, 3C (claims 1, 2, 6, and 8) in the reply filed on November 26, 2005 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
- 2. Claims 3-5, 7, 9 are 10-13 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Group and species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on November 26, 2005.
- 3. Applicant's election with traverse of N-WASP output domain, SH3 and PDZ input domains in the reply filed on February 5, 2006 is acknowledged. The traversal is on the ground(s) that the invention can be applied to essentially any output and input domain providing a desired activity. This is not found persuasive because claim 8 specifically states that the input domain should cooperatively regulate the output domain as an AND-gate. Furthermore, the various domains listed in the specification pertain to different subject matter as different protein domains are classified applied differently in the art of protein engineering.

The requirement is still deemed proper and is therefore made FINAL.

4. Species of output and input domains other than N-WASP output domain, SH3 and PDZ input domains are withdrawn from further consideration pursuant to 37 CFR

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1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on February 5, 2006.

Claim Rejections - 35 USC § 112

VAGUE AND INDEFINITE

- 1. The following is a quotation of the second paragraph of 35 U.S.C. 112:
 - The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 2. Claims 1, 2, 6, and 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
- 3. Claim 1 recites "external, ligand-dependently" which is unclear because it is the input domain that regulates the output domain. The input domains are external to the output domains and so are any binding ligands. The claim can be interpreted as reciting the limitation that input domain regulate the output domain as a result of any externally binding ligand. The claim can also be interpreted as reciting the limitation that input domains externally regulate the output domains. Clarification is requested.
- 1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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SCOPE OF ENABLEMENT

Claims 1, 2, 6, and 8 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an autoregulated protein with an N-WASP output domain, SH3 and PDZ input domains, does not reasonably provide enablement for an autoregulated protein with all of the output and input domains listed in the Tables of the specification. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The specification does not provide guidance for making an autoregulated protein with a set of interacting input and output domains other than with an N-WASP output domain and SH3 and PDZ input domains. There is insufficient guidance for engineering any autoregulated fussion protein that will "allosterically and external, ligand dependently regulate the output domain.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in Exparte Forman, 230 USPQ 546 (BPAI 1986) and reiterated by the Court of Appeals in In re Wands, 8 USPQ2d 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breath of the claims.

The Board also stated that although the level of skill in molecular biology is high, the results of experiments in genetic engineering are unpredictable. While all of these factors are considered, a sufficient amount for a *prima facie* case are discussed below which leads to the determination that the above claim lacks enablement due to undue experimentation being required to make and use the invention.

- (1) the quantity of experimentation necessary to successfully create a polynucleotide chimera that will express a protein is large. The specification lists a multitude of domains and recites in claim 1 that the protein's input domains will regulate the output domains. Although there is description in the "Detailed Example" (pages 20-27) for the making of function of an autoregulated protein with an N-WASP output domain, SH3 and PDZ input domains, there is insufficient description for how to achieve the synthesis of such an autoregulated protein using all of the domains listed in the specification.
- (3) the specification provides a working example describing an autoregulated protein with an N-WASP output domain, SH3 and PDZ input domains. However, there is not a representative sample of experiments to cover the multitude of input and output domains that are recited as being able to comprise such an autoregulated protein. The one Detailed Example is insufficient to describe the making of an autoregulated protein for any of the domains listed in the specification and only describes the one specific autoregulated protein with an N-WASP output domain, SH3 and PDZ input domains.
- (4) the nature of the invention is complex and there is insufficient description in the specification to enable the making and use of the multitude of different

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autoregulated proteins possible with various combinations of output an input domains listed in the Tables. There is not enough in the specification to enable a general autoregulated protein that will "allosterically and external, ligand-dependently regulate the output domain" for all the domains listed in the specification. The only autoregulated protein described in the specification is one with an N-WASP output domain, SH3 and PDZ input domains. The complexity of creating a fusion protein that will function properly as described in claim 1 warrants more examples and descriptions to enable the invention.

- (7) It is highly unpredictable if the combination of domains listed in the specification will successfully lead to an autoregulating protein where the input domains interact with each other and regulate the output domain. Though the idea of creating such a protein is expressed in the specification, there is insufficient evidence that the protein is enabled for all the listed domains.
 - (8) the breath of the claim is extremely broad

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anna Skibinsky whose telephone number is (571) 272-4373. The examiner can normally be reached on 8 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Anna Skibinsky, PhD

JOHN S. BRUSCA, PH.D